

U.S. Application No.  
Unknown

International Application No.  
PCT/AU00/00652

Attorney Docket No.  
DAVI152.001APC

Date: December 10, 2001

10/009946 Page 1

**TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 USC 371**

International Application No.: PCT/AU00/00652  
International Filing Date: June 9, 2000  
Priority Date Claimed: June 10, 1999  
Title of Invention: DISPOSABLE LANCET DEVICE  
Applicant(s) for DO/EO/US: Napoleon Curie

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. (X) This is a **FIRST** submission of items concerning a filing under 35 USC 371.
2. () This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 USC 371.
3. (X) This express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 USC 371(b) and PCT Articles 22 and 39(1).
4. (X) A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. (X) A copy of the International Application as filed (35 USC 371(c)(2))
  - a) () is transmitted herewith (required only if not transmitted by the International Bureau).
  - b) () has been transmitted by the International Bureau.
  - c) (X) a copy of Form PCT/1B/308 is enclosed.
  - d) () is not required, as the application was filed in the United States Receiving Office (RO/US).
6. () A translation of the International Application into English (35 USC 371(c)(2)).
7. (X) Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3))
  - a) () are transmitted herewith (required only if not transmitted by the International Bureau).
  - b) () have been transmitted by the International Bureau.
  - c) () have not been made; however, the time limit for making such amendments has NOT expired.
  - d) (X) have not been made and will not be made.
8. () A translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3)).
9. (X) An oath or declaration of the inventor(s) (35 USC 371(c)(4)).
10. (X) A copy of the International Preliminary Examination Report with any annexes thereto, such as any amendments made under PCT Article 34.
11. () A translation of the annexes, such as any amendments made under PCT Article 34, to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)).

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12. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
13. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
14. ☒ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☒ Form PCT/IPEA/402 accompanied with Form PCT/IPEA/401
17. ☒ International Application as published.
18. ☒ The present application qualifies for small entity status under 37 C.F.R. § 1.27.
19. ☒ International Search Report.
20. ☒ A return prepaid postcard.
21. ☒ The following fees are submitted:

				FEES
BASIC FEE				\$1,040
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total Claims	30 - 20 =	10 ×	\$18	\$180
Independent Claims	2 - 3 =	0 ×	\$84	\$0
Multiple dependent claims(s) (if applicable)			\$280	\$0
TOTAL OF ABOVE CALCULATIONS				\$1,220
Reduction by 1/2 for filing by small entity (if applicable). Verified Small Entity statement must also be filed. (NOTE 37 CFR 1.9, 1.27, 1.28)				\$610
TOTAL NATIONAL FEE				\$610
TOTAL FEES ENCLOSED				\$610
amount to be refunded:				\$0
amount to be charged:				\$0

22. ☒ A check in the amount of \$610 to cover the above fees is enclosed.

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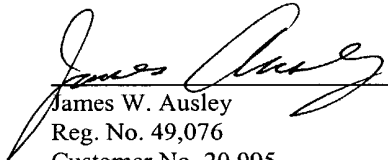
Date: December 10, 2001

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23. (X) Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property.
24. (X) The Commissioner is hereby authorized to charge only those additional fees which may be required, now or in the future, to avoid abandonment of the application, or credit any overpayment to Deposit Account No. 11-1410.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

  
James W. Ausley  
Reg. No. 49,076  
Customer No. 20,995

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DAVI152.001APC

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Napolean Curie	)	Group Art Unit Unknown
			)	
PCT Appl. No.:		PCT/AU00/00652	)	
			)	
Filed	:	Herewith	)	
			)	
For	:	DISPOSABLE LANCET	)	
		DEVICE	)	
			)	
Examiner	:	Unknown	)	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Prior to examination, please amend the above referenced application as follows:

**IN THE ABSTRACT:**

Please delete the abstract and insert the following amended abstract:

--Abstract of the Disclosure

A disposable lancet device adapted to pierce human skin sufficiently to let a small quantity of blood for testing. The device includes a lancet housing, a lancet body displaceably supported by the housing, and a piercing tip concealed within the housing in a rest position. The piercing tip can be integral with the lancet body or attached thereto. The device also includes an actuator for manually displacing the lancet body to expose the piercing tip under applied force and a return mechanism that returns the lancet body to the rest position when the manual displacement force is removed from the actuator. The actuator can be disabled to inhibit further manual displacement of the lancet body and exposure of the piercing tip. Thus, the piercing tip

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Filed : Herewith

can be repeatedly exposed if desired, but can also be disabled once further use is no longer desired.—

**IN THE SPECIFICATION:**

Page 1, immediately after the title, please insert —Related applications This application claims the benefit of the Australian application PQ 0892 filed June 10, 1999 and the international application PCT/AU00/00652 filed June 9, 2000.—

**IN THE CLAIMS:**

Please amend the Claims as follows:

1. (Amended) A disposable lancet device for piercing human skin comprising:  
a lancet housing;  
a lancet body displaceably supported by the housing and having a piercing tip which is concealed within the housing in a rest position of the body;  
an operator engaged with the lancet body for manually displacing the lancet body to expose the piercing tip; and  
a return against which the lancet body operates as it is manually displaced to expose the piercing tip whereby the return automatically retracts the lancet body to its rest position when the manual displacement force is removed from the operator wherein the operator is adapted to be disengaged from the lancet body after use to prevent subsequent manual displacement of the lancet body from its rest position.
2. (Amended) The disposable lancet device of claim 1, wherein manual force applied to the operator is translated to the lancet body for displacing the lancet body from its rest position.
3. (Amended) The disposable lancet device of claim 1, wherein the return holds the lancet body in its rest position.
4. (Amended) The disposable lancet device of claim 1, wherein the return comprises at least one resilient projection extending from the lancet body, wherein the resilient projection is deformed by a portion of the housing when the lancet body is displaced from its rest position.

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5. (Amended) The disposable lancet device of claim 1, wherein the return comprises at least one resilient projection extending from the housing, wherein the resilient projection is deformed by a portion of the lancet body when the lancet body is displaced from its rest position.

6. (Amended) The disposable lancet device of claim 1, wherein the return comprises a coil spring.

7. (Amended) The disposable lancet device of claim 1, wherein the lancet body is supported for linear displacement by the housing.

8. (Amended) The disposable lancet device of claim 1, wherein the operator is disposed on the axis of displacement of the lancet body.

9. (Amended) The disposable lancet device of claim 1, wherein the lancet body, operating means and piercing tip form a generally elongate member.

10. (Amended) The disposable lancet device of claim 1, wherein the lancet body is non-linearly displaceable.

11. (Amended) The disposable lancet device of claim 10, wherein the operator projects from the housing to one side of the lancet body.

12. (Amended) The disposable lancet device of claim 1, wherein the operator is integrally moulded with the lancet body.

13. (Amended) The disposable lancet device of claim 12, wherein the operator is breakable from the lancet body at a line of weakness at or adjacent the juncture of the lancet body with the housing when the lancet body is in its rest position.

14. (Amended) The disposable lancet device of claim 1, wherein the operator is connected to the lancet body by a connection device.

15. (Amended) The disposable lancet device of claim 14, wherein the connection device is a snap engaging connection or screw thread.

16. (Amended) The disposable lancet device of claim 1, wherein the piercing tip is secured to the lancet body.

17. (Amended) The disposable lancet device of claim 1, wherein the piercing tip is integral with the lancet body.

18. (Amended) The disposable lancet device of claim 16, wherein the lancet body is moulded around a mounting portion of the tip.

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19. (Amended) The disposable lancet device of claim 1, wherein the piercing tip and lancet body are moulded from the same or different plastics material selected from polycarbonate, polystyrene, and polypropylene.

20. (Amended) The disposable lancet device of claim 18, wherein the piercing tip is formed of metal.

21. (Amended) The disposable lancet device of claim 1, wherein the piercing tip has a cylindrical body tapering to a pointed end.

22. (Amended) The disposable lancet device of claim 1, wherein the piercing tip is multi-sided.

23. (Amended) The disposable lancet device of claim 22, wherein the tip is pyramidal or flat with sharp leading edges.

Please add the following new Claims:

24. (New) The disposable lancet device of Claim 20, wherein the metal comprises stainless steel.

25. (New) A multi-use, safety lancet device comprising:

a lancet housing of a first length;

a lancet body displacably positioned within the lancet housing;

a piercing tip attached to a first end of the lancet body such that the piercing tip and lancet body together are of a second length less than the first length;

a return biasing the lancet body and piercing tip to a concealed position wherein the lancet housing covers the piercing tip; and

an actuator operating the lancet body between the concealed and an operational positions wherein the piercing tip is exposed and wherein the actuator can repeatedly change between the concealed and operational positions and wherein the actuator is also disableable so as to inhibit further achievement of the operational position.

26. (New) The device of Claim 25, wherein the piercing tip and the lancet body are an integral part.

27. (New) The device of Claim 25, wherein the actuator is attached to the second end of the lancet body opposite the piercing tip such that the actuator, lancet body, and piercing tip together form a lancet assembly having a third length greater than the first length.

$$= \frac{1}{\sqrt{2}} \begin{pmatrix} -\frac{\sqrt{3}}{2} & \frac{1}{2} \\ \frac{1}{2} & \frac{\sqrt{3}}{2} \end{pmatrix} \begin{pmatrix} \frac{1}{2} & \frac{\sqrt{3}}{2} \\ -\frac{\sqrt{3}}{2} & \frac{1}{2} \end{pmatrix} = \frac{1}{2} \begin{pmatrix} -\frac{\sqrt{3}}{2} + \frac{3}{2} & \frac{1}{2} + \frac{\sqrt{3}}{2} \\ \frac{1}{2} - \frac{3}{2} & \frac{\sqrt{3}}{2} + \frac{1}{2} \end{pmatrix} = \frac{1}{2} \begin{pmatrix} \frac{-\sqrt{3}+3}{2} & \frac{1+\sqrt{3}}{2} \\ -1 & \frac{\sqrt{3}+1}{2} \end{pmatrix}$$

- REMARKS

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 12/10/01

by: James W. Ausley  
James W. Ausley  
Registration No. 49,076

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Filed : Herewith

10/009946  
JC05 Rec'd PCT/PTO 10 DEC 2007

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE ABSTRACT:**

[57 Abstract: This invention relates to a disposable lancet device which may be used to pierce human skin sufficiently to let a small quantity of blood for testing. It comprises a lancet housing (12), a lancet body (14) displaceably supported by the housing (12) and having a piercing tip (52) which is concealed within the housing (12) in a rest position of the body (14). It also comprises operating means (46) for manually displacing the lancet body (14) to expose the piercing tip (52). It includes biasing means (36) against which the lancet body (14) operates as it is manually displaced to expose the piercing tip (52), whereby the biasing means (36) automatically retracts the lancet body (14) to its rest position when the manual displacement force is removed from the operating means (46). Disabling the operating means (46) prevents manual displacement of the lancet body (14) from its rest position.]

**--Abstract of the Disclosure**

**A disposable lancet device adapted to pierce human skin sufficiently to let a small quantity of blood for testing. The device includes a lancet housing, a lancet body displaceably supported by the housing, and a piercing tip concealed within the housing in a rest position. The piercing tip can be integral with the lancet body or attached thereto. The device also includes an actuator for manually displacing the lancet body to expose the piercing tip under applied force and a return mechanism that returns the lancet body to the rest position when the manual displacement force is removed from the actuator. The actuator can be disabled to inhibit further manual displacement of the lancet body and exposure of the piercing tip. Thus, the piercing tip can be repeatedly exposed if desired, but can also be disabled once further use is no longer desired.--**

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Filed : Herewith

**IN THE SPECIFICATION:**

Page 1, immediately after the title, please insert –**Related applications** **This application claims the benefit of the Australian application PQ 0892 filed June 10, 1999 and the international application PCT/AU00/00652 filed June 9, 2000.—**

**IN THE CLAIMS:**

Please amend the Claims as follows:

1. (Amended) A disposable lancet device for piercing human skin comprising:  
a lancet housing;  
a lancet body displaceably supported by the housing and having a piercing tip which is concealed within the housing in a rest position of the body;  
[operating means] **an operator** engaged with the lancet body for manually displacing the lancet body to expose the piercing tip; and  
[biasing means] **a return** against which the lancet body operates as it is manually displaced to expose the piercing tip whereby the [biasing means] **return** automatically retracts the lancet body to its rest position when the manual displacement force is removed from the [operating means] **operator** wherein the [operating means] **operator** is adapted to be disengaged from the lancet body after use to prevent subsequent manual displacement of the lancet body from its rest position.
2. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein manual force applied to the [operating means] operator is translated to the lancet body for displacing the lancet body from its rest position.
3. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [biasing means] **return** holds the lancet body in its rest position.
4. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [biasing means] **return** comprises at least one resilient projection extending from the lancet body, wherein the resilient projection is deformed by a portion of the housing when the lancet body is displaced from its rest position.
5. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [biasing means] **return** comprises at least one resilient projection extending from the housing, wherein the resilient projection is deformed by a portion of the lancet body when the

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lancet body is displaced from its rest position.

6. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [biasing means] **return** comprises a coil spring.

7. (Amended) [A] **The disposable lancet device [according to] of claim 1,**  
wherein the lancet body is supported for linear displacement by the housing.

8. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [operating means] **operator** is disposed on the axis of displacement of the lancet body.

9. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the lancet body, operating means and piercing tip form a generally elongate member.

10. (Amended) [A] **The disposable lancet device** [according to] **of** claim 1, wherein the lancet body is non-linearly displaceable.

11. (Amended) [A] **The disposable lancet device** [according to] **of claim 10,**  
wherein the [operating means] **operator** projects from the housing to one side of the lancet body.

12. (Amended) [A] **The disposable lancet device** [according to] **of** claim 1, wherein the [operating means] **operator** is integrally moulded with the lancet body.

13. (Amended) [A] **The** disposable lancet device [according to] **of** claim 12, wherein the [operating means] **operator** is breakable from the lancet body at a line of weakness at or adjacent the juncture of the lancet body with the housing when the lancet body is in its rest position.

14. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [operating means] **operator** is connected to the lancet body by a connection device.

15. (Amended) [A] **The** disposable lancet device [according to] **of** claim 14, wherein the connection device is a snap engaging connection or screw thread.

16. (Amended) [A] **The disposable lancet device** [according to] **of** claim 1, wherein the piercing tip is secured to the lancet body.

17. (Amended) [A] **The disposable lancet device** [according to] **of** claim 1, wherein the piercing tip is integral with the lancet body.

18. (Amended) [A] **The disposable lancet device** [according to] **of** claim 16, wherein the lancet body is moulded around a mounting portion of the tip.

19. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1,

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wherein the piercing tip and lancet body are moulded from the same or different plastics material selected from polycarbonate, polystyrene, and polypropylene.

20. (Amended) [A] **The** disposable lancet device [according to] **of** claim 18, wherein the piercing tip is formed of metal [, preferably stainless steel].

21. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the piercing tip has a cylindrical body tapering to a pointed end.

22. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the piercing tip is multi-sided.

23. (Amended) [A] **The** disposable lancet device [according to] **of** claim 22, wherein the tip is pyramidal or flat with sharp leading edges.

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**DISPOSABLE LANCET DEVICE**

This invention relates to a disposable lancet device which may be used to pierce human skin sufficiently to let a small quantity of blood for testing. In particular, it relates to a disposable lancet device of a relatively simple construction which can be used several times by a single user, but also has a disabling feature which can prevent reuse.

Lancet devices are currently available which enable a small quantity of blood to be let from an incision in human skin. Some diseases necessitate the testing of blood at regular intervals. For instance, diabetes requires testing for glucose content of blood and this may be performed on a day to day basis by many patients. As such, lancet devices which pierce the skin to let an adequate amount of blood for testing are required for use by patients in the home and also for use by nurses or medical technicians who routinely conduct such tests on patients.

In cases where several patients are tested consecutively, there is often a risk of a spread of infection by the use of a single lancet device on more than one patient. Furthermore, in instances of home use the problem of erroneous results may arise if a lancet device which has previously been used is used again some time later and has retained remnants of old blood which are subsequently included in the testing procedure. In order to counteract such problems devices which can only be used once have been proposed. Although these devices solve the problems addressed above they introduce a further problem in circumstances where a device fails to incise the skin on the first attempt, or if a device is accidentally activated, as a further attempt to incise the skin is not possible. Examples of lancet devices which can only be used once are shown in US Patents 4,735,203 and 5,554,166. The inability to repeat a failed attempt at incising the skin and the necessity of using a second device introduces additional costs to the consumer.

The problem of risk of infection may also arise if the needle or piercing tip of the lancet device is exposed and accidentally pricks a nurse or technician after the device has been used. Safety features enabling automatic retraction of the needle after piercing of the skin

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involve complicated mechanisms which usually include a large number of components resulting in a device which is expensive to manufacture. Examples of proposed lancet devices of a complicated nature with a large number of components are given in US Patents 5,554,166, mentioned above, and 5,741,288.

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According to the present invention there is provided a disposable lancet device for piercing human skin comprising:

a lancet housing,

a lancet body displaceably supported by the housing and having a piercing tip which is  
10 concealed within the housing in a rest position of the body,

operating means engaged with the lancet body for manually displacing the lancet body to expose the piercing tip, and

biasing means against which the lancet body operates as it is manually displaced to expose the piercing tip whereby the biasing means automatically retracts the lancet body to its rest

15 position when the manual displacement force is removed from the operating means,

wherein the operating means is adapted to be disengaged from the lancet body after use to prevent subsequent manual displacement of the lancet body from its rest position.

The lancet device according to the present invention addresses the above problems in that  
20 it can be used several times by a single user, either in the home or by a person administering the incision, so that a first attempt can be repeated if it does not succeed.

The device can also be disabled permanently to prevent reuse and has a concealed tip to alleviate accidental piercing of the skin. The device may also have a relatively simple construction. In particular, it avoids the use of complicated spring-loaded mechanisms in  
25 order to achieve successful incision of the skin.

The piercing tip is advantageously integral with the lancet body, and may be moulded with the lancet body in a plastics material such as polycarbonate, polystyrene or polypropylene. Polypropylene may not provide the tip with adequate piercing ability in which case  
30 polystyrene is preferred. In this embodiment, the tip is preferably formed of metal such as stainless steel. The tip may have a cylindrical body tapering to a pointed end, but

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preferably it is multi-sided, for example, pyramidal or flat with sharp leading edges to cut rather than just puncture the skin.

The lancet body is preferably supported for linear displacement by the housing, in which case the operating means is conveniently disposed on the axis of displacement of the lancet body, at the opposite end to the piercing tip. Thus, advantageously, the lancet body, operating means and piercing tip form a generally elongate member. However, the lancet body may be non-linearly displaceable and/or the operating means may project from the housing to one-side of the lancet body. The operating means may be connected to the lancet body by a screw thread or other connection device such as a snap-engaging means which facilitates ready separation from the lancet body to disable the lancet device after use. However, preferably the operating means is integrally moulded with the lancet body and is breakable therefrom at a line of weakness at or adjacent the juncture with the housing when the lancet body is in its rest position.

Only a short application of pressure to the manual operating means is required in use of the lancet device, such that the pressure applied to the operating means is translated to the lancet body for displacing the lancet body from its rest position, so that when the device is held against a person's skin, the piercing tip is exposed long enough to cause an incision and produce an adequate amount of blood for testing. Once manual pressure is removed from the operating means, the lancet body is automatically retracted back to the rest position with the piercing tip within the housing due to the operation of the biasing means. The biasing means may hold the lancet body in its rest position. The biasing means can take any of many forms.

In one embodiment, the biasing means comprises at least one resilient projection or leaf spring in the housing which is deformed by the lancet body or operating means as the lancet body is displaced out of its rest position. Preferably, the or each resilient projection may be attached to the housing. Further preferably, the or each resilient projection is integral with the housing and, for example, may conveniently be moulded with the housing.

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Alternatively, the or each resilient projection or leaf spring, or other form of biasing means, may be integral with or attached to the lancet body, and is deformed by the housing as the lancet body is displaced out of its rest position.

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In another embodiment, the biasing means may comprise a coil spring within the housing which is deformed by the lancet body or operating means as the lancet body is displaced out of its rest position.

10 One embodiment of a disposable lancet device in accordance with the present invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1 is a front elevational view of the disposable lancet device, with the front removed  
15 for clarity;

Figure 2 is a sectional view along line AA of Figure 1, with the front cover in place and the lancet body removed; and

Figure 3 is a side view of the lancet body.

20

#### DETAILED DESCRIPTION OF THE DRAWINGS

The lancet device 10 shown in the Figures comprises a housing 12 and a lancet body 14. The housing 12 is preferably moulded in polypropylene and has a front wall 18 spaced  
25 from a rear wall 16 by opposed side walls 20 and a top wall 22 extending between the side walls. The front wall 18 may be moulded separately to the remainder of the housing to facilitate the location of the lancet body 14 in the housing, or it may be integrally hinged to the remainder of the housing, for example along a join line (not shown) at the top wall 22. Either way, the front wall may be secured to the side walls 20 and top wall 22 by any  
30 suitable means including bonding with a bonding agent, heat sealing, ultrasonic or other welding or snap-engaging or other connection devices.



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The housing 12 defines a passage 24 between the front and rear walls through which the lancet body 14 is manually displaceable. At one end of the passage, an opening 26 is provided in the top wall 22. At the other, the housing tapers to an opposed opening 28.

5 Above the tapered portion 30, the housing provides opposed planar gripping surfaces 32 on the front and rear walls, both of which may be used to hold the device 10 at least until the lancet body is actuated.

Within the housing a pair of opposed stop members 34 extend from the respective side  
10 walls 20 towards each other to define a portion of the passage 24 therebetween. The stop members 34 are integrally moulded with the side walls and with the rear wall 16. Between the stop members 34 and the tapered portion 30 of the housing 12, a pair of opposed leaf springs 36 project towards each other from the side walls 20 to define another portion of the passage 24 therebetween. In contrast to the stop members 34, the leaf springs are  
15 separate from both the front and rear walls 18 and 16 so that their distal end portions 38 can resiliently flex along the passage 24. The leaf springs 36 are conveniently integral with the side walls 20 and therefore preferably injection moulded in polypropylene, but they may be separately formed, for example, in stainless steel, and for example, located in slots (not shown) in the respective side walls.

20

The lancet body 14 has a shaft 40 and a pair of opposed rigid wing members 42 each sized to be received between the respective stop member 34 and leaf spring 36. At its proximal end 44, the lancet body 14 has a manual operating knob 46 connected to the lancet body by a weakened portion 48 formed, for example, of reduced diameter compared to the proximal  
25 end 44 and knob 46. At its distal end 50 the lancet body 14 has a piercing tip 52 which may take any suitable form to provide a cutting point or blade. Preferably, as shown, the piercing tip is in the form of a narrow cutting edge 54.

Preferably, the lancet body 14 is also injection moulded in polypropylene, but if  
30 insufficient sharpness of the piercing tip 52 can be achieved with this material, it may instead be injection moulded in, for example, polystyrene or polycarbonate. Alternatively,

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instead of injection moulding the piercing tip 52 integrally with the remainder of the lancet body, it may be formed separately in the desired material and secured to the remainder of the lancet body.

5 The length of the shaft 40 and the relative position of the wing members 42 are such that with the wing members in the rest position between the stop members 34 and leaf springs 36 shown in Figure 1, the operating knob 46 projects from the housing 12 with the weakened portion 48 at the juncture with the housing, but the piercing tip 52 is concealed within the tapered portion 30 of the housing. Preferably, the operating knob 46 projects  
10 sufficiently from the top wall 22 that when it is manually pressed so as to be flush with the top wall the piercing tip 52 is exposed sufficiently to just pierce the skin of the finger 56 of the patient whose blood is being let when the finger 56 is engaged with the tapered end 28 of the housing 12.

15 In order to assemble the device 10, the operating knob 46 is passed outwardly through the opening 26 in the top wall 22 with the front wall 18 open or removed and the shaft 40 is disposed in the passage 24 with the members 42 between the respective stop members 34 and leaf springs 36. The front wall 18 is then secured to the side walls 20 and/or top wall 22, and the device is subjected to sterilisation.

20

As described above, in use, the operating knob 46 is displaced manually downwardly by pressure applied directly via the thumb or forefinger of the user to expose the piercing tip 52 and pierce the skin of the patient's finger 56. The manual displacement of the knob 46 and therefore of the shaft 40 causes the wing members 42 to resiliently deform the leaf  
25 springs 36 which then automatically retract the shaft and piercing tip 52 when the manual pressure is removed from the operating knob 46. When the lancet body 14 is returned to its rest position shown in Figure 1 by the leaf springs 36, the operating knob 46 is again exposed and may be broken off at the weakened portion 48 to prevent re-use.

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Those skilled in the art will appreciate that the invention described therein is susceptible to variations and modifications other than those specifically described. It is to be understood that the invention includes all such variations and modifications which fall within its spirit and scope.

5

The reference to any prior art in this specification is not, and should not be taken as an acknowledgment or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

- 10 Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

15

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## CLAIMS

1. A disposable lancet device for piercing human skin comprising:  
a lancet housing,  
5 a lancet body displaceably supported by the housing and having a piercing tip  
which is concealed within the housing in a rest position of the body,  
operating means engaged with the lancet body for manually displacing the lancet  
body to expose the piercing tip, and  
biasing means against which the lancet body operates as it is manually displaced to  
10 expose the piercing tip whereby the biasing means automatically retracts the lancet  
body to its rest position when the manual displacement force is removed from the  
operating means,  
wherein the operating means is adapted to be disengaged from the lancet body after  
use to prevent subsequent manual displacement of the lancet body from its rest  
15 position.
2. A disposable lancet device according to claim 1, wherein manual force applied to  
the operating means is translated to the lancet body for displacing the lancet body from its  
rest position.  
20
3. A disposable lancet device according to claim 1, wherein the biasing means holds  
the lancet body in its rest position.
4. A disposable lancet device according to claim 1, wherein the biasing means  
25 comprises at least one resilient projection extending from the lancet body, wherein the  
resilient projection is deformed by a portion of the housing when the lancet body is  
displaced from its rest position.
5. A disposable lancet device according to claim 1, wherein the biasing means  
30 comprises at least one resilient projection extending from the housing, wherein the resilient  
projection is deformed by a portion of the lancet body when the lancet body is displaced

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from its rest position.

6. A disposable lancet device according to claim 1, wherein the biasing means comprises a coil spring.

5

7. A disposable lancet device according to claim 1, wherein the lancet body is supported for linear displacement by the housing.

8. A disposable lancet device according to claim 1, wherein the operating means is disposed on the axis of displacement of the lancet body.

10

9. A disposable lancet device according to claim 1, wherein the lancet body, operating means and piercing tip form a generally elongate member.

10. A disposable lancet device according to claim 1, wherein the lancet body is non-linearly displaceable.

15

11. A disposable lancet device according to claim 10, wherein the operating means projects from the housing to one side of the lancet body.

20

12. A disposable lancet device according to claim 1, wherein the operating means is integrally moulded with the lancet body.

13. A disposable lancet device according to claim 12, wherein the operating means is breakable from the lancet body at a line of weakness at or adjacent the juncture of the lancet body with the housing when the lancet body is in its rest position.

25

14. A disposable lancet device according to claim 1, wherein the operating means is connected to the lancet body by a connection device.

30

15. A disposable lancet device according to claim 14, wherein the connection device is

- 10 -

a snap engaging connection or screw thread.

16. A disposable lancet device according to claim 1, wherein the piercing tip is secured to the lancet body.

5

17. A disposable lancet device according to claim 1, wherein the piercing tip is integral with the lancet body.

18. A disposable lancet device according to claim 16, wherein the lancet body is  
10 moulded around a mounting portion of the tip.

19. A disposable lancet device according to claim 1, wherein the piercing tip and lancet body are moulded from the same or different plastics material selected from polycarbonate, polystyrene and polypropylene.

15

20. A disposable lancet device according to claim 18, wherein the piercing tip is formed of metal, preferably stainless steel.

21. A disposable lancet device according to claim 1, wherein the piercing tip has a  
20 cylindrical body tapering to a pointed end.

22. A disposable lancet device according to claim 1, wherein the piercing tip is multi-sided.

23. A disposable lancet device according to claim 22, wherein the tip is pyramidal or flat with sharp leading edges.

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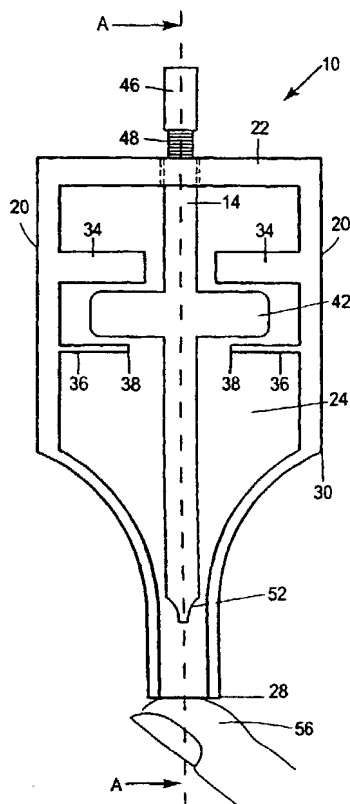
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[Continued on next page]

(54) Title: **DISPOSABLE LANCET DEVICE**



(57) Abstract: This invention relates to a disposable lancet device which may be used to pierce human skin sufficiently to let a small quantity of blood for testing. It comprises a lancet housing (12), a lancet body (14) displaceably supported by the housing (12) and having a piercing tip (52) which is concealed within the housing (12) in a rest position of the body (14). It also comprises operating means (46) for manually displacing the lancet body (14) to expose the piercing tip (52). It includes biasing means (36) against which the lancet body (14) operates as it is manually displaced to expose the piercing tip (52), whereby the biasing means (36) automatically retracts the lancet body (14) to its rest position when the manual displacement force is removed from the operating means (46). Disabling the operating means (46) prevents manual displacement of the lancet body (14) from its rest position.

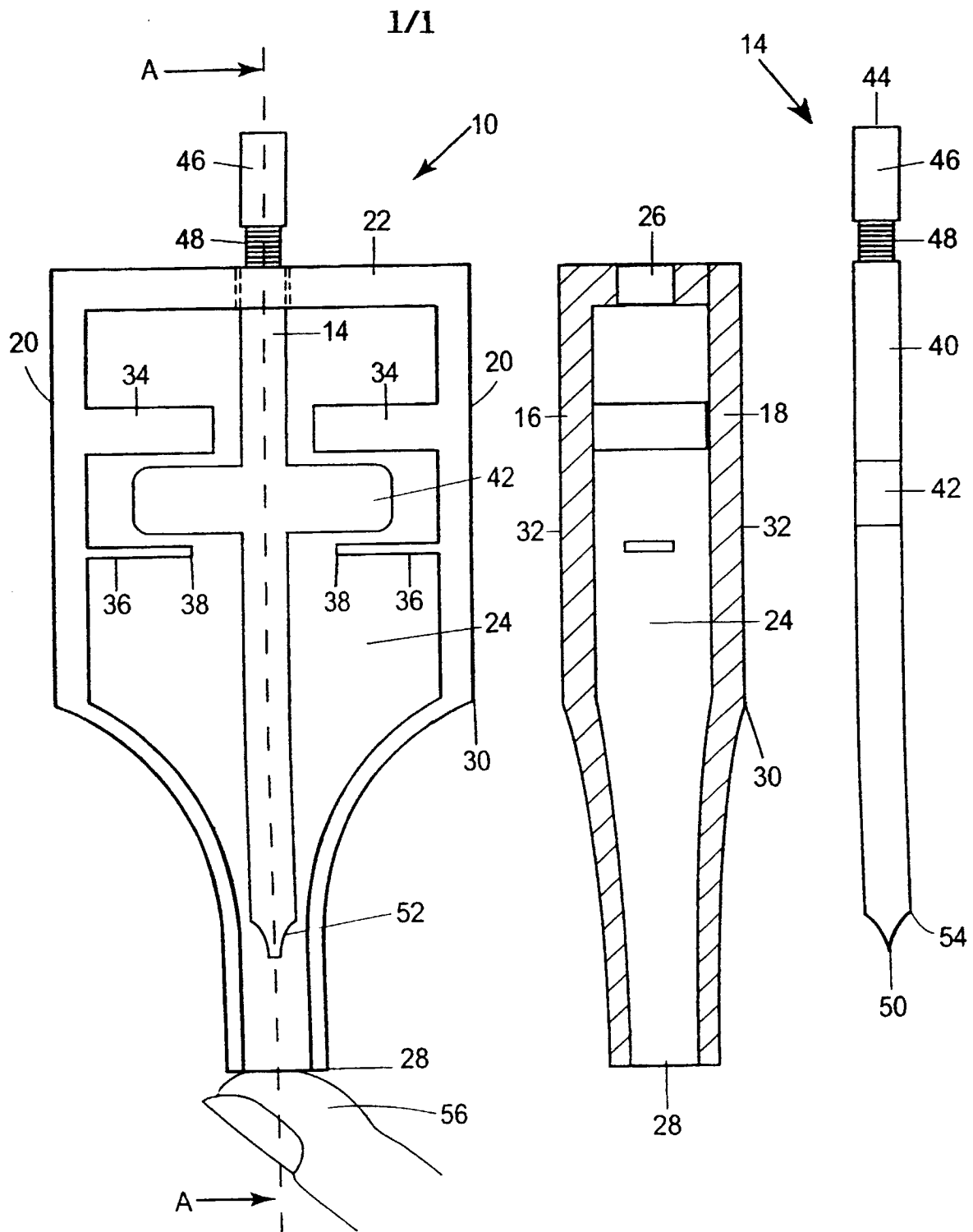
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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*





**FIG 1**

**FIG 2**

**FIG 3**

**DECLARATION AND POWER OF ATTORNEY - USA PATENT APPLICATION**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled DISPOSABLE LANCET DEVICE

the specification of which:

- (a) ☐ is attached hereto; or
- (b) ☐ was filed on \_\_\_\_\_ as ☐ Application No. 0 / \_\_\_\_\_ or ☐ Express Mail No., as Application No. not yet known \_\_\_\_\_ and was amended on \_\_\_\_\_ (if applicable); or
- (c) ☒ was described and claimed in PCT International Application No. PCT/AU00/00652 filed on 9 June, 2000 and as amended under PCT Article 19 on \_\_\_\_\_ (if any) and/or under PCT Article 34 on 3 April, 2001 (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56;

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent, design or inventor's certificate or any PCT international application(s) listed below and have also identified below any foreign application(s) for patent, design or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed for the same subject matter having a filing date before that of the application(s) of which priority is claimed:

**PRIOR FOREIGN APPLICATION(S)**

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 U.S.C. § 119
Australia	PQ 0892/99	10 June, 1999	<input checked="" type="checkbox"/> YES NO <input type="checkbox"/>
PCT	PCT/AU00/00652	9 June, 2000	<input checked="" type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
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I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below, and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S.A. Application(s)

Application No.: \_\_\_\_\_ Filing Date: \_\_\_\_\_ Status: \_\_\_\_\_

POWER OF ATTORNEY: I hereby appoint the registrants of Knobbe, Martens, Olson & Bear, LLP, 620 Newport Center Drive, Sixteenth Floor, Newport Beach, California 92660, Telephone (714) 760-0404, Customer No. 20,995, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith (if this application is assigned, I acknowledge that the appointed individuals do not represent me, and that instead they represent the assignee).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

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